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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,328	12/07/1999	KUBER T. SAMPATH	CIBT-P01-514	9813

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	11

DATE MAILED: 05/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/445,328	SAMPATH ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The restriction requirement mailed 07/02/01 (Paper No. 6) is withdrawn. A new restriction requirement is set forth below.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 5-38, to the extent that they are drawn to a method of treatment for a mammal in, or at risk of, acute renal failure comprising administering OP-1.

Group II, Claim(s) 1, 5-38, to the extent that they are drawn to a method of treatment for a mammal in, or at risk of, acute renal failure comprising administering OP-2.

Group III, Claim(s) 1, 5-38, to the extent that they are drawn to a method of treatment for a mammal in, or at risk of, acute renal failure comprising administering OP-3.

Group IV, Claim(s) 1, 5-38, to the extent that they are drawn to a method of treatment for a mammal in, or at risk of, acute renal failure comprising administering BMP2.

Group V, Claim(s) 1, 5-38, to the extent that they are drawn to a method of treatment for a mammal in, or at risk of, acute renal failure comprising administering BMP3.

Group VI, Claim(s) 1, 5-38, to the extent that they are drawn to a method of treatment for a mammal in, or at risk of, acute renal failure comprising administering BMP4.

Group VII, Claim(s) 1, 5-38, to the extent that they are drawn to a method of treatment for a mammal in, or at risk of, acute renal failure comprising administering BMP5.

Group VIII, Claim(s) 1, 5-38, to the extent that they are drawn to a method of treatment for a mammal in, or at risk of, acute renal failure comprising administering BMP6.

Group IX, Claim(s) 1, 5-38, to the extent that they are drawn to a method of treatment for a mammal in, or at risk of, acute renal failure comprising administering BMP9.

Group X, Claim(s) 2, 5-38, to the extent that they are drawn to a method of treatment to delay the need for, or reduce the frequency of, dialysis comprising administering OP-1.

Group XI, Claim(s) 2, 5-38, to the extent that they are drawn to a method of treatment to delay the need for, or reduce the frequency of, dialysis comprising administering OP-2.

Group XII, Claim(s) 2, 5-38, to the extent that they are drawn to a method of treatment to delay the need for, or reduce the frequency of, dialysis comprising administering OP-3.

Group XIII, Claim(s) 2, 5-38, to the extent that they are drawn to a method of treatment to delay the need for, or reduce the frequency of, dialysis comprising administering BMP2.

Group XIV, Claim(s) 2, 5-38, to the extent that they are drawn to a method of treatment to delay the need for, or reduce the frequency of, dialysis comprising administering BMP3.

Group XV, Claim(s) 2, 5-38, to the extent that they are drawn to a method of treatment to delay the need for, or reduce the frequency of, dialysis comprising administering BMP4.

Group XVI, Claim(s) 2, 5-38, to the extent that they are drawn to a method of treatment to delay the need for, or reduce the frequency of, dialysis comprising administering BMP5.

Group XVII, Claim(s) 2, 5-38, to the extent that they are drawn to a method of treatment to delay the need for, or reduce the frequency of, dialysis comprising administering BMP6.

Group XVIII, Claim(s) 2, 5-38, to the extent that they are drawn to a method of treatment to delay the need for, or reduce the frequency of, dialysis comprising administering BMP9.

Group XIX, Claim(s) 3, 5-14, 25-38, to the extent that they are drawn to a method of reducing inflammation comprising administering OP-1.

Group XX, Claim(s) 3, 5-14, 25-38, to the extent that they are drawn to a method of reducing inflammation comprising administering OP-2.

Group XXI, Claim(s) 3, 5-14, 25-38, to the extent that they are drawn to a method of reducing inflammation comprising administering OP-3.

Group XXII, Claim(s) 3, 5-14, 25-38, to the extent that they are drawn to a method of reducing inflammation comprising administering BMP2.

Group XXIII, Claim(s) 3, 5-14, 25-38, to the extent that they are drawn to a method of reducing inflammation comprising administering BMP3.

Group XXIV, Claim(s) 3, 5-14, 25-38, to the extent that they are drawn to a method of reducing inflammation comprising administering BMP4.

Group XXV, Claim(s) 3, 5-14, 25-38, to the extent that they are drawn to a method of reducing inflammation comprising administering BMP5.

Group XXVI, Claim(s) 3, 5-14, 25-38, to the extent that they are drawn to a method of reducing inflammation comprising administering BMP6.

Group XXVII, Claim(s) 3, 5-14, 25-38, to the extent that they are drawn to a method of reducing inflammation comprising administering BMP9.

Group XXVIII, Claim(s) 4, 5-14, 25-38, to the extent that they are drawn to a method of inhibiting apoptosis comprising administering OP-1.

Group XXIX, Claim(s) 4, 5-14, 25-38, to the extent that they are drawn to a method of inhibiting apoptosis comprising administering OP-2.

Group XXX, Claim(s) 4, 5-14, 25-38, to the extent that they are drawn to a method of inhibiting apoptosis comprising administering OP-3.

Group XXXI, Claim(s) 4, 5-14, 25-38, to the extent that they are drawn to a method of inhibiting apoptosis comprising administering BMP2.

Group XXXII, Claim(s) 4, 5-14, 25-38, to the extent that they are drawn to a method of inhibiting apoptosis comprising administering BMP3.

Group XXXIII, Claim(s) 4, 5-14, 25-38, to the extent that they are drawn to a method of inhibiting apoptosis comprising administering BMP4.

Group XXXIV, Claim(s) 4, 5-14, 25-38, to the extent that they are drawn to a method of inhibiting apoptosis comprising administering BMP5.

Group XXXV, Claim(s) 4, 5-14, 25-38, to the extent that they are drawn to a method of inhibiting apoptosis comprising administering BMP6.

Group XXXVI, Claim(s) 4, 5-14, 25-38, to the extent that they are drawn to a method of inhibiting apoptosis comprising administering BMP9.

Group XXXVII, Claim(s) 39-52, to the extent that they are drawn to use of OP-1 for the manufacture of a medicament.

Group XXXVIII, Claim(s) 39-52, to the extent that they are drawn to use of OP-2 for the manufacture of a medicament.

Group XXXIX, Claim(s) 39-52, to the extent that they are drawn to use of OP-3 for the manufacture of a medicament.

Group XL, Claim(s) 39-52, to the extent that they are drawn to use of BMP2 for the manufacture of a medicament.

Group XLI, Claim(s) 39-52, to the extent that they are drawn to use of BMP3 for the manufacture of a medicament.

Group XLII, Claim(s) 39-52, to the extent that they are drawn to use of BMP4 for the manufacture of a medicament.

Group XLIII, Claim(s) 39-52, to the extent that they are drawn to use of BMP5 for the manufacture of a medicament.

Group XLIV, Claim(s) 39-52, to the extent that they are drawn to use of BMP6 for the manufacture of a medicament.

Group XLV, Claim(s) 39-52, to the extent that they are drawn to use of BMP9 for the manufacture of a medicament.

The inventions listed as Groups I-XLV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: With respect to unity of invention PCT Rule 13.1 states "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention")." Additionally, PCT Rule 13.2 states: "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of

the claimed inventions, considered as a whole, makes over the prior art." Groups I-XLV lack technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See documents D1, D2, D3, or D4 cited in the international search report filed with the instant application. It is further known in the prior art to use each of OP-1, OP-2, OP-3, BMP2, BMP3, BMP4, BMP5, BMP6, and BMP9 for the manufacture of a medicament.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

(1) The species are as follows: a pro form, a mature form, and a soluble form of OP-1. The claims are deemed to correspond to the species listed above in the following manner: Claims 1-6 correspond to each of the species listed above. The following claim(s) are generic: 1-6.

(2) The species are as follows: pre-renal causes of acute renal failure, post-renal causes of acute renal failure, and intrinsic renal causes of acute renal failure. The claims are deemed to correspond to the species listed above in the following manner: Claims 1-22 correspond to each of the species listed above. The following claim(s) are generic: 1-22.

(2)(a) For said species of pre-renal causes of acute renal failure this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive

concept under PCT Rule 13.1. The species are listed in claim 20. Claims 1-20 correspond to each of the species listed above. The following claim(s) are generic: 1-20.

(2)(b) For said species of post-renal causes of acute renal failure this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are listed in claim 21. Claims 1-19, 21 correspond to each of the species listed above. The following claim(s) are generic: 1-19, 21.

(2)(c) For said species of intrinsic renal causes of acute renal failure this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are listed in claim 22. Claims 1-19, 22 correspond to each of the species listed above. The following claim(s) are generic: 1-19, 22.

(3) The species are as follows: A single species in any one of claims 25-29. The claims are deemed to correspond to the species listed above in the following manner: Claims 1-29 correspond to each of the species listed above. The following claim(s) are generic: 1-29.

(3)(a) For said single species in claim 26 this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are a single species in any one of claims 31-34. Claims 1-26, 30 correspond to each of the species listed above. The following claim(s) are generic: 1-26, 30.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the same reasons above that Groups I-XLV do not relate to a single general inventive concept under PCT Rule 13.1.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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DSR
MAY 2, 2002